



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0145]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Improving Food Safety and Defense Capacity of the State and Local Level: Review of State and Local Capacities

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-NEW and title “Improving Food Safety and Defense Capacity of the State and Local Level: Review of State and Local Capacities.” Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Improving Food Safety and Defense Capacity of the State and Local Level: Review of State and Local Capacities--(OMB Control Number 0910-New)

The Food Safety Modernization Act (FSMA) (Public Law 111-353) states in section 205(c)2 that a review must be conducted to assess the State and local government capacities to show needs for enhancement in the areas of staffing levels, laboratory capacities, and information technology systems. This mandate is referenced again in FSMA section 110, stating that a review of current food safety and food defense capabilities must be presented to Congress no later than 2 years after the date of enactment (enactment date January 4, 2011). In order to facilitate this review, a survey will be distributed to State and local health and agriculture agencies. Results of the survey will be used to analyze the gaps and trends in capacity that occurs at the State and local government levels. Results of the analyses will enable FSMA partners to develop strategies to enhance food safety and food defense capacity. In developing these strategies, FDA will be able to work with other Federal, State and local Agencies to

improve and expand food safety and defense to ultimately reach a state of an integrated food safety system.

The survey will be conducted electronically, which allows FDA to conduct streamlined analysis while creating a low-burden, user-friendly environment for respondents to complete the survey. Once the results have been tabulated, a report will be generated and given to the FSMA section 110 work group to present to Congress as well as the FSMA section 205(c)1 work group to develop strategies to leverage and enhance current State and local capacities.

In the Federal Register of February 24, 2012 (77 FR 11132), FDA published a 60-day notice requesting public comment on the proposed collection of information. The Agency received six comments. The comments, and the Agency's responses, are discussed in the following paragraphs.

(Comment 1) FDA conducted a review of existing surveys.

(Response) Although helpful, these surveys did not fully address factors such as laboratory capacity and information technology in State and local agencies. Therefore, this survey will be used to fill the gaps of various other surveys so that FDA can meet its objective as congressionally mandated in FSMA.

(Comment 2) The proposed information collection is necessary for the proper performance of FDA's functions.

(Response) FDA believes that this comment does not address the proposed information collection.

(Comment 3) The National Association of County and City Health Officials (NACCHO) recommends FDA builds upon information gathered from existing food safety and defense assessments and surveys.

(Response) Prior to developing this survey, FDA conducted a systematic review of current and past surveys conducted by Federal, State, and local Agencies, academia, industry, and associations such as the Association of Food and Drug Officials (AFDO), the Association of State and Territorial Health Officials, and NACCHO's 2008 survey regarding budget cuts and reductions of State and local agencies. This review revealed that the current and past surveys did not contain sufficient information for FDA to establish and analyze possible gaps in the areas of food safety, food defense, laboratories, and information technology. The results of the review of current and past surveys were conveyed to an FDA working group focused on drafting a report to Congress that is specified by FSMA section 110. Under section 110, FDA has a congressionally mandated deadline to conduct a more extensive review by January 4, 2013, which will require the support of section 205(c)2. FDA was aware that NACCHO was conducting a survey but due to time restrictions, FDA could not wait for NACCHO's survey to be made public prior to developing the current survey. Also, FDA did not know the content of NACCHO's survey and how it would address the needs of obtaining information to support FSMA section 205(c)2.

(Comment 4) FDA should survey 1,400 State and local agencies at minimum instead of focusing on 1,400 State and local employees.

(Response) FDA is proposing to survey 1,400 State and local agencies. The involvement of single or multiple individuals from a single agency will be left to the discretion of the responding entity.

(Comment 5) NACCHO recommends that the assessment be designed to allow multiple employees within an agency access to the survey on multiple occasions to fully and accurately complete the survey.

(Response) FDA has an arrangement with AFDO, through a cooperative agreement, to deliver the survey, but at this time, the exact mechanism for delivering the survey has not been established. FDA will take into consideration NACCHO's suggestion of developing a Web-based portal with log in capability to allow multiple users to log in to the same survey to increase the efficiency of completing the survey. In addition, hardcopies of the survey can be made available upon request.

(Comment 6) The assessment should be conducted on a routine basis.

(Response) FDA agrees with NACCHO in its statement that a survey, such as this one, should be conducted on a more regular basis to track and trend gaps. At this time, this survey is intended to be a one-time collection of information. FDA could consider conducting future surveys, depending on Agency resources and priorities.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Current State and local government agencies	1,400	1	1,400	1	1,400

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

This survey is slated to be a one-time survey. Through testing on six FDA employees who were former State employees, the survey development team has concluded that it should take no longer than 1 hour for the 1,400 current State and local government agencies to complete the survey. FDA is requesting this data collection burden so as not to restrict the Agency's ability to gather information on public sentiment for its proposals in its regulatory and communications programs.

Dated: May 24, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

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